

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

USDC SDNY DOCUMENT ELECTRONICALLY FILED DOC #: DATE FILED: 07/05/2022
---

-----X  
 (RC) 2 PHARMA CONNECT, LLC,

Plaintiff,

-v-

MISSION PHARMACAL COMPANY,

Defendant.  
 -----X

21-cv-11096 (LJL)

OPINION AND ORDER

LEWIS J. LIMAN, United States District Judge:

Defendant Mission Pharmacal Company (“Defendant” or “Mission”) moves, pursuant to Federal Rule of Civil Procedure 12(b)(6), for an order dismissing the first amended complaint (“Complaint”) against it or, in the alternative, pursuant to Federal Rule of Civil Procedure 12(f), to strike portions of the complaint. Dkt. No. 34.

For the following reasons, the motion to dismiss is granted.

### BACKGROUND

The Court accepts as true the well-pleaded allegations of the Complaint and the documents incorporated by reference.

Plaintiff (RC) Pharma Connection, LLC (“(RC) 2” or “Plaintiff”) is a pharmaceutical broker that specializes in sourcing and developing chemicals, pharmaceutical ingredients, and pharmaceutical products in cooperation with manufacturing partners that operate manufacturing facilities all over the world. Dkt. No. 8 ¶ 1. Its members are Dwight E. Raff II, Jason G. Raff, and William T. Cain. *Id.* ¶ 18. Mission is a pharmaceutical company involved in, *inter alia*, the development and manufacture of pharmaceuticals as a contract partner for third parties. *Id.* ¶ 2. Its general counsel is Thomas James, who joined the company in 2020. Dkt. No. 8 ¶¶ 3, 20, 23.

## **I. The Parties' Initial Relationship**

Defendant was retained by Plaintiff to assist in the development of a generic version of a topical medication used to treat a common virus that causes cold sores. The medication is known under the brand name "Abreva," and the generic version is docosanol 10% cream.

The relationship between Plaintiff and Defendant is governed by two agreements.

### **A. The NDA**

In January 2019, Plaintiff and Defendant executed a non-disclosure agreement ("NDA"), effective January 2019, related to the development of docosanol 10% cream. *Id.* ¶¶ 29–32. The NDA permitted the parties to each share confidential information with the other and required the recipient "to protect and safeguard the confidentiality" of that information and not to use the disclosing party's confidential information for any purpose other than "discussions regarding docosanol 10% cream" (defined as the "Purpose") "or any related transactions between the Parties." Dkt. No. 8-1 § 3(a), (b). It defined "Confidential Information" to include "the Disclosing Party's unpatented inventions, ideas, methods and discoveries, trade secrets, know-how, unpublished patent applications and other confidential intellectual property." *Id.* § 1(b).

### **B. The Proposal Agreement**

In March 2019, Plaintiff signed a Proposal Agreement dated March 13, 2019 for Defendant to perform activities to "support the development of a formulation and process for, preparation of and submission of an ANDA<sup>1</sup> for, and commercial launch of Docosanol 10%

---

<sup>1</sup> An ANDA is an Abbreviated New Drug Application. It contains data and is submitted to the FDA for the review and potential approval of a generic drug product. *See Abbreviated New Drug Application (ANDA)*, FDA, <https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda> (last visited July 5, 2022); *see also In re Bystolic Antitrust Litig.*, 2022 WL 594534, at \*3 (S.D.N.Y. Jan. 31, 2022), *redacted opinion issued*, 2022 WL 323945 (S.D.N.Y. Feb. 2, 2022) (describing ANDA process).

cream,” subject to a successful facility visit on April 10, 2019; after the visit, (RC) 2 re-executed the agreement on May 17, 2019. Dkt. No. 8 ¶¶ 47–48; Dkt. No. 8-2. The Proposal Agreement contains a scope of work for Mission “to perform activities required to support the validation and production of launch stocks for Docosanol 10% cream” in five phases: Initial Development, Method Development, Technical Transfer, ANDA Preparation, and Commercialization and Validation. As relevant here, Phase 3 (Technical Transfer) requires Mission to manufacture three batches of the product at scales identified in the agreement and to conduct stability testing and leachable and extractable testing and to test for “contact elemental impurities.” Dkt. No. 8-2 § 2.3. The Proposal Agreement explicitly contemplates that certain of the work (extractables/leachables and polymorph analysis) will be “outsourced.” *Id.* §§ 3.2, 3.4. It provides that (RC) 2 would be charged at an hourly rate of \$250 an hour for Mission internal resources time spent on investigations and that “[c]osts of items sent to our Pharmacovigilance third party provider and cost for any external testimony required as part of an investigation” would be billed at cost. *Id.* § 3.7.2. The Proposal Agreement contemplates that work will be done in phases. The first phase would be initiation followed by initial development and method development before technical transfer of materials, and then preparation of an ANDA, and finally commercialization and validation. Phase 4, which follows Phase 3, requires Mission to complete a development report, to compile all data and review as necessary, and to compose and file an ANDA. Finally, Phase 5 is commercialization and validation.

In calculating an estimated unit pricing, the Proposal Agreement assumes that Mission would procure all required ingredients and packaging materials, that (RC) 2 would supply the docosanol active pharmaceutical ingredient, and that the parties would reach a five-year manufacturing agreement. The Proposal Agreement has a provision with respect to Project

Management which requires Mission to conduct the work detailed under the supervision of an Account Manager, who would be the primary point of contact between the parties. Dkt. No. 8-2 § 5. On May 23, 2019, Mission sent (RC) 2 an undated proposed supply agreement, which contained New York personal jurisdiction, venue, and choice of law provisions. Dkt. No. 8-4; Dkt. No. 8 ¶ 52. Plaintiff never signed the agreement.

## **II. The Parties' Disagreement over the Technology Transfer Agreement**

The relationship between the parties apparently began smoothly. Beginning soon after they entered into the Proposal Agreement, the parties held regular—typically bi-weekly—phone calls to discuss upcoming technical issues and deadlines. Mission provided an agenda before each of these phone calls. Dkt. No. 8 ¶ 59; *see also, e.g.*, Dkt. No. 8-5 (containing minutes of a meeting held on July 15, 2021 that reflect the parties' discussion of stability testing on the three batches, 39X21, 40X21, and 41X21, and the parties' discussion that, with respect to the extractable leaching study, legal was requesting that a Technology Transfer Agreement be completed first). However, the relationship between the parties shifted after Mission's General Counsel, James, became more actively involved in Mission's relationship with (RC) 2. Dkt. No. 8 ¶ 60.

On or about December 23, 2020, Mission sent (RC) 2 a proposed Technology Transfer Agreement (“TTA”) and stated that Mission's “Legal Dept. is instituting Technical Transfer agreements for all existing and new projects.” *Id.* ¶ 67. The proposed TTA provided that Mission would perform a number of technology transfer activities, including manufacturing registration batches of the product and successfully completing stability testing of the six-month timepoint samples, with test results to be submitted to the FDA for product approval and registration. It also contemplated that thereafter (RC) 2 would enter into a manufacturing and supply agreement with Mission for the delivery of the commercial product. The draft TTA

contained a section for the fees Mission would receive. It also contained a provision that “[s]o long as (RC) 2 [wa]s current in its payments to Mission . . . , any and all potential patents that (RC) 2 obtain[ed] that are related to formulations unique to the Product shall be owned by (RC) 2 and not Mission,” Dkt. No. 13-11 ¶ 10.12, and that, provided that Mission had been paid all sums due to it, Mission would immediately cease to use any and all intellectual property exclusively owned by (RC) 2 including patents. The TTA also contained an arbitration clause and a provision that, while (RC) 2 would own its intellectual property, Mission would own certain of its intellectual property relating to the process and methodologies used to manufacture docosanol 10% cream. *Id.* ¶ 70.

(RC) 2 provided proposed revisions to the TTA on July 19, 2021. *Id.* ¶ 71; Dkt. No. 13-11 at ECF p. 2. In an email of that date, (RC) 2 noted that it had made “two substantive changes” to Mission’s draft agreement. The first had to do with the patent and data rights. (RC) 2 stated that it could “accept that Mission would own any technology and accompanying patent rights for innovations discovered while working on this project.” Dkt. No. 13-11 at ECF p. 2–3. It added: “However, as RC2 has funded this work we would also expect a royalty-free, worldwide license for the use of any such technology on the 10% docosanol cream.” *Id.*; *see also* Dkt. No. 8 ¶¶ 71–72. The second change related to the choice of law governing the agreement. Dkt. No. 8 ¶ 71. Mission returned the draft TTA to Plaintiff on September 2, 2021. Dkt. No. 13-11. Mission struck out the language referring to “an exclusive, royalty-free license assigned to RC2 for all applications involving 10% docosanol cream” as well as language inserted by Plaintiff that Plaintiff would *exclusively* own all potential patents related to formulations unique to the Product (leaving the language that (RC) 2 would own the potential patents). *Id.* at ECF p. 14. In comment bubbles to the changes, Mission’s James stated:

Mission can make the affirmative statement that as between the parties of RC2 and Mission that RC2 (and not Mission) will own any patents that RC2 is able to obtain on the formulation of its product, but Mission cannot make any statement as to “possible uses” or “exclusivity” of RC2’s ownership of anything that RC2 has not yet obtained, which is why these clarifying, marked changes have been made in this Section 10.12(a).

No. Mission is not granting any license in the processes or methodologies used by Mission to make this Product nor in any “applications” involving the Product. Mission is the sole owner of the processes and methodologies used by Mission in its know-how to make any product, including but not limited to this particular Product.

*Id.*

The September 2, 2021 email contains the last draft of the proposed TTA exchanged between the parties. Dkt. No. 54 ¶ 2.

Testy communications ensued between the parties. On September 3, 2021, Jason Raff of (RC) 2 responded to the proposed modifications, saying “[t]he proposed modifications to the Technology Transfer agreement are no[t] acceptable to us as proposed to your attorney,” and asking that Mission “advise next steps, if any,” but stating that (RC) 2 does “not feel compelled to execute the agreement [Mission] wishes to put in place in its current form.” Dkt. No. 54-2 at ECF p. 7. James, of Mission, responded the same day, saying that “the positions taken by Mission in the draft agreement with your company are completely appropriate and will continue to be required if your company desires to conduct business with Mission.” *Id.* at ECF p. 6. James stated unequivocally: “If your company desires to engage in business with Mission, then it will be under the draft agreement that Mission has provided to you without change. If your company does not desire to engage in business with Mission under the terms of the agreement that has been provided by Mission to your company, then we thank you for the opportunity to work with your company and we wish you and your company all the best in your future activities.” *Id.* Raff responded later that day: “[W]e have been working with Mission for nearly

2 years and spent hundreds of thousands of dollar[s] with your company. Are you saying that you will just abandon this program because we don't agree with the language you are trying to force on us? Is Mission going to refund the money that we have spent?" *Id.* at ECF p. 5. James responded to Raff that Mission would not refund any of the payments it had received from (RC) 2 for previous work and then doubled down on his seeming ultimatum: "As clearly stated in my below email to you, Mission is willing to work with your company under the terms of the agreement that has been provided to your company by Mission. However, Mission will not agree to the subject changes from your company to such agreement." *Id.* at ECF p. 4. Raff responded that "[t]he work done by Mission to date is useless and of no value unless continued" and asked why the agreement wasn't "brought to us up front before we spent two years of time and hundreds of thousands of dollars." *Id.* He added that "[t]rying to change the program now because of this agreement sounds like really bad faith as a minimum and blackmail in the extreme." *Id.* James responded—still on September 3—by denying that there is any "bad faith, blackmail or any other untenable action by Mission in this matter or any other matter" but once again reiterating his position that "[i]f you desire to move forward with Mission, then we can do so under the agreement that Mission has provided to your company" and stating "[i]f you decide to utilize another company, then that is certainly your choice in which case we wish you all the best in your future activities." *Id.* at ECF p. 3. James then responded to the same email a week later, reiterating the same position:

The senior management of Mission Pharmacal Company has met and further discussed your company's requested changes to the Technology Transfer Agreement. We understand your company's requested changes and the stated reasons for desiring such changes, but Mission very respectfully does not concur with such requested changes to the agreement. Mission and your company have each made investments in a mutual relationship together that Mission genuinely desires to continue with your company, but the continuation of such a valued

relationship, which we hope will be the case, will be required to be under the agreement that Mission has provided to your company.

*Id.* at ECF p. 2.

### **III. The Parties' Continuing Relationship**

Despite the breakdown between the parties over the TTA negotiations, the docosanol 10% project continued, as contemplated by the Proposal Agreement. Pursuant to that agreement, (RC) 2 had generated three registration batches of docosanol 10% cream (39X21, 40X21, and 41X21) that needed to undergo various internal and outsourced stability testing at various time periods. *Id.* ¶¶ 86–87, 89. Each of the registration batches includes docosanol 10% cream packed in tubes and in containers with a hand pump. *Id.* ¶ 88. The time parameters of the Proposal Agreement require long-term stability tests to be conducted at time zero, one month, three months, six months, nine months, twelve months, eighteen months, and twenty-four months; accelerated stability tests to be conducted at thirty days, ninety days, and 180 days; and intermediate conditions stability tests to be conducted at ninety days, 180 days, 270 days, and 360 days. *Id.* ¶ 89. Pursuant to the Proposal Agreement, and because of the logistics associated with the storage and gathering of the stability testing specimens, the stability testing must be performed by Mission. *Id.* ¶¶ 89, 100. The six-month stability pulls for the first of the three batches were scheduled to be gathered on December 21, 2021, for stability testing to be completed by the deadline of December 31, 2021. *Id.* ¶¶ 93, 107. The six-month stability pulls for the other two batches were scheduled to be gathered on January 12, 2022 to permit Defendant to perform the six-month stability testing on those samples by the deadline of January 31, 2022. *Id.* ¶ 97. If the six-month stability pulls for 39X21 were not timely gathered, the two other



registration batches (40X21 and 41X21) would also be rendered inviable for stability testing.<sup>2</sup> *Id.* ¶ 110.

(RC) 2 alleges, upon information and belief, that—with the exception of the stability tests that form the basis of its breach of contract claims—Mission “has performed the required stability tests for 39X21, 40X21 and 41X21.” *Id.* ¶ 91. (RC) 2 also alleges that Mission’s “communications suggest that it has timely initiated the six-month stability testing” but that “its representations . . . confirm that it is willing to cease compliance with its obligations in the middle of performance,” and “it is not clear whether Mission will complete the six-month stability testing for 39X21.” *Id.* ¶ 96. (RC) 2 further alleges that “[w]hile Mission’s communications suggest that it has gathered the materials and begun to perform the six-month stability testing, it has not confirmed that it will complete the necessary testing as is required by the Proposal Agreement.” *Id.* ¶ 99. (RC) 2 states that Mission’s “performance (i.e., completion) of the six-month stability testing remains in question.” *Id.* ¶ 99. It also alleges that communications from Mission’s counsel “do not confirm that Mission will complete stability testing of 39X21, or perform any other necessary testing on 39X21.” *Id.* ¶ 109.

Pursuant to the Proposal Agreement, Mission is required to engage third parties to perform: (1) extractables/leachables studies to determine whether the product extracts any materials into the packaging and whether the packaging leaches into the product; and (2) polymorphic and rheology studies to determine whether there is any undissolved docosanol in the product and, if so, its polymorphic form. *Id.* ¶ 102. The third-party studies require the

---

<sup>2</sup> Moreover, if any of the six-month stability pulls is not tested pursuant to the governing timelines, the entire project subject to the Proposal Agreement will be ruined, and Plaintiff will be forced to restart its product development and ANDA submission efforts, delaying the time to market by at least one year. *Id.* ¶ 112.

analysis of several materials that are exclusively in Mission’s control, including samples of the six-month stability pulls as well as other samples of the three registration batches and placebo materials. *Id.* Those third-party studies then provide Mission with necessary information for it to incorporate into the ANDA submission. *Id.* ¶ 103. (RC) 2 has the ability to engage third party laboratories to perform the studies; however, in that scenario it would still need Mission to provide it certain materials that are exclusively within Mission’s possession, including the samples from the registration batches, samples of the six-month stability pulls, and the placebo samples. *Id.* ¶ 104. Moreover, if Mission does not timely collect the six-month stability pulls, the third-party studies will not be timely performed and the entire ANDA submission process pursuant to the Proposal Agreement will be irreparably destroyed. *Id.* ¶ 105.

On December 16 and December 17, 2021, (RC) 2 contacted Mission regarding the upcoming critical deadlines and requested confirmation that Mission would perform its obligations to cause the relevant testing to be performed. *Id.* ¶ 115. In its December 16, 2021, email, (RC) 2 expressed concern that Mission “either has not or will not uphold its obligations per the parties’ continuing agreement” and, in particular, requested “proof in writing” or “confirm[ation] in writing” that Mission had conducted the extractables/leachables studies and polymorphic and rheology studies. Dkt. No. 8-3 at 7. The email expressed the hope that (RC) 2’s concerns were unfounded but asked for “confirmation” before the close of business on December 22, 2021 so that (RC) 2 would be “able to keep to the timeline we built into the governing agreement with [Defendant].” *Id.* On December 17, 2022, Raff of (RC) 2, forwarded the email to Tom Dooley of Mission, expressing concern regarding Mission’s future compliance with the Proposal Agreement and requesting a telephone call. The email ended with the statement: “I’d like the lawyers not to be involved in our call. Our strong preference is to avoid

litigation.” Dkt. No. 8-3 at 2–3. On December 20, 2021, Mission responded that its “legal department ha[d] stated that all communications between RC2 and Mission will need to go through them, and so I will be canceling our team call.” Dkt. No. 8-3 at 6; *see also* Dkt. No. 8 ¶ 118.

(RC) 2 followed up on December 21, 2021 to request confirmation by December 22, 2021 of the items in its December 16, 2021 email. Dkt. No. 8 ¶¶ 116–117; Dkt. No. 8-3 at 5. It also stated its understanding that the six-month stability pull for 39X21 had occurred as scheduled but asked for confirmation that Mission was continuing with the registration stability studies for that batch as well as that Mission would execute the six-month stability pulls for 40X21 and 41X21 on January 12, 2022 and would continue the registration stability studies for those batches as well. Dkt. No. 8-3 at 8. The email concluded that (RC) 2 would take a failure to confirm these points by December 22, 2021 to be “confirmation” that Mission had not performed the requested actions and planned not to perform them on January 12, 2022. Dkt. No. 8 ¶ 117. Defendant did not respond by the end of the day on December 22, 2021. *Id.* ¶ 119.

(RC) 2 states it instituted this action on December 24, 2021, alleging claims for breach of contract and anticipatory breach of contract.<sup>3</sup> *Id.* ¶ 121. (RC) 2 has attached to its Amended Complaint the settlement communications that followed the commencement of the lawsuit. Counsel for Mission wrote to counsel for (RC) 2 on the early afternoon of December 28, 2021, asking what needed to be done regarding stability testing and asking (RC) 2 to identify proposed logistics for Mission to provide the samples to (RC) 2 or its third-party vendors in connection

---

<sup>3</sup> December 24, 2021 was a Court holiday. On Monday, December 27, 2021, the Honorable Vernon L. Broderick permitted Plaintiff to file papers under seal. Dkt. No. 3. The docket reflects that the complaint was accepted for filing the following Tuesday, December 28, 2021. Dkt. No. 1. Apparently, on December 24, 2021, (RC) 2 emailed a copy of its Complaint to Mission. Dkt. No. 35 at 3 n.1.

with the extractables/leaching and polymorphic/rheology testing. Dkt. No. 8-6 at 6–7. Mission’s counsel sent another email an hour and a half later making sure that (RC) 2’s counsel had received the earlier communication. *Id.* at 6. On the evening of December 28, 2021, (RC) 2’s counsel emailed Mission’s counsel, asking for confirmation that Mission had initiated the stability pull of 39X21 on December 21, 2021 and was in the process of performing the stability testing of that batch for timely completion and suggesting that the parties get on the phone so that (RC) 2 could understand where the various testing processes stood. *Id.* at 4. The following day—December 29—Mission’s counsel wrote to (RC) 2’s counsel with the confirmation that Mission had initiated the six-month stability pull of batch 39X21 on December 21, 2021 and was in the process of performing stability testing for that batch and that it planned to pull the six-month samples for batches 40X21 and 41X21 on January 12, 2022; Mission also stated that, if (RC) 2 was not able to perform stability testing with a third party for those batches that Mission might be willing to do so. *Id.* at 2. With respect to the non-stability testing that the Proposal Agreement contemplated would be outsourced, Mission noted that it did not perform that kind of testing itself and that (RC) 2 “did not agree to the vendors suggested by Mission that Mission has utilized in the past for this type of work.” *Id.* It therefore stated that (RC) 2 would “need to utilize its preferred vendors for all such non-stability work.” *Id.* It went on to state that (RC) 2 “will need to use third-parties other than Mission for any other activities that were previously performed by Mission, including but not limited to (i) any future work of any type, (ii) any development work or validation testing for an IVRT method, (iii) all testing and analyses on Abreva samples.” *Id.* at 2–3. The communication also included a proposal for the termination of the business relationship between the parties and Mission’s agreement to accept service of process of the initial complaint. *Id.* at 3.

RC (2) alleges that the December 29 communication from counsel constitutes confirmation that Mission intends to breach the Proposal Agreement. Dkt. No. 8 ¶ 123. (RC) 2 alleges that Mission and James “know very well that it is not possible [for (RC) 2 to continue to develop its product with another partner] and Mission’s suggestion to the contrary are disingenuous.” *Id.* ¶ 81.

### **PROCEDURAL HISTORY**

Plaintiff’s initial complaint was accepted for filing on December 28, 2021. Dkt. No. 1. The first amended complaint was filed on December 29, 2021. Dkt. No. 8. Plaintiff also sought an order to show cause why the Court should not issue a temporary restraining order compelling Defendant to comply with the terms of the Proposal Agreement. Dkt. No. 9. The Court held a telephonic conference on the order to show cause on January 3, 2022. Dkt. No. 22. At that time, Plaintiff withdrew its request for a temporary restraining order and a preliminary injunction, and Defendant withdrew its corresponding request for sanctions and attorneys’ fees.

Defendant filed its motion to dismiss and an accompanying memorandum of law in support of the motion to dismiss on February 18, 2022. Dkt. Nos. 34–35. Plaintiff filed its memorandum of law in opposition to the motion to dismiss on March 11, 2022, Dkt. No. 42, and Defendant filed a reply memorandum in further support of its motion to dismiss on March 25, 2022, Dkt. No. 47. Plaintiff also filed a motion for leave to file a sur-reply in opposition to Defendant’s motion to dismiss, Dkt. No. 49; that motion is denied. The argument to which Plaintiff seeks to respond is not relevant to the Court’s decision here.

On April 25, 2022, Plaintiff filed a second order to show cause why the Court should not issue a temporary restraining order “enjoining the defendant . . . from further breaching its agreements with plaintiff” in various ways. Dkt. No. 57.

## DISCUSSION

### I. Defendant’s Motion to Dismiss

#### A. Legal Standard

On a 12(b)(6) motion to dismiss, a court must accept as true all factual allegations in the complaint and draw all possible inferences from those allegations in favor of the plaintiff. *See York v. Ass’n of the Bar of the City of N.Y.*, 286 F.3d 122, 125 (2d Cir. 2002), *cert. denied*, 537 U.S. 1089 (2002). This requirement “is inapplicable to legal conclusions.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Thus, “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* A complaint must offer more than “labels and conclusions,” or “a formulaic recitation of the elements of a cause of action” or “naked assertion[s]” devoid of “further factual enhancement” in order to survive dismissal. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 557 (2007). The ultimate question is whether “[a] claim has facial plausibility, [i.e.] the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. “Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.* at 679. Put another way, the plausibility requirement “calls for enough fact to raise a reasonable expectation that discovery will reveal evidence [supporting the claim].” *Twombly*, 550 U.S. at 556; *see also Matrixx v. Siracusano*, 563 U.S. 27, 46 (2011).

#### B. Analysis

(RC) 2’s Complaint asserts three claims against Mission: (1) Count 1, for breach of the NDA; (2) Count 2, for breach of the Proposal Agreement; and (3) Count 3, for anticipatory breach of the Proposal Agreement. Dkt. No. 8.

### 1. Count 1: Breach of the NDA

(RC) 2 first claim for relief is for an alleged breach of the NDA. (RC) 2 alleges that it provided Mission with certain confidential information necessary for Mission to develop docosanol 10% cream and to prepare the ANDA for submission—including but not limited to its proprietary formula and manufacturing process and know-how required for the manufacture of its docosanol 10% cream—and that based on James’ statement that Mission would not grant (RC) 2 an exclusive license to technology related to developing docosanol 10% cream, it has reason to believe that Mission has breached or intends to the NDA. It alleges that, based on Mission’s refusal to grant an exclusive license, it has reason to believe that Mission intends to manufacture and supply docosanol 10% cream to third-party distributors and/or to act as a distributor and to sell docosanol 10% cream that it has manufactured and that the sale of such cream to anyone other than (RC) 2 would constitute a use of (RC) 2’s confidential information in violation of the NDA. Dkt. No. 8 ¶¶ 128–131.

“To prevail on a breach of contract claim under New York law, a plaintiff must prove ‘(1) a contract; (2) performance of the contract by one party; (3) breach by the other party; and (4) damages.’” *Terwilliger v. Terwilliger*, 206 F.3d 240, 246 (2d Cir. 2000) (quoting *First Investors Corp. v. Liberty Mutual Insurance Co.*, 152 F.3d 162, 168 (2d Cir. 1998)); *see also Mancuso v. L’Oreal USA, Inc.*, 2021 WL 1240328, at \*3 (S.D.N.Y. Apr. 2, 2021) (“[T]here are four elements to a breach of contract claim: (1) the existence of an agreement, (2) adequate performance of the contract by the plaintiff, (3) breach of contract by the defendant, and (4) damages.” (internal quotation marks omitted) (quoting *Ellington Credit Fund, Ltd. v. Select Portfolio Servicing, Inc.*, 837 F. Supp. 2d 162, 188–89 (S.D.N.Y. 2011))). “[T]he plaintiff’s allegations must identify the provisions of the contract that were breached.” *Canzona v. Atanasio*, 989 N.Y.S.2d 44, 47 (2nd Dep’t 2014) (quoting *Barker v Time Warner Cable, Inc.*,

923 N.Y.S.2d 118, 120 (2011) (citing cases)). That is, it is “an essential requirement for a breach of contract claim” that Plaintiff identify the specific provisions of a contract that it alleges the defendant has violated. *Gallo v. Inter-Con Security Systems Inc.*, 2021 WL 3913539, at \*9 (S.D.N.Y. Sept. 1, 2021) (internal quotation marks omitted) (quoting *Orange County Choppers, Inc. v. Olaes Enters., Inc.*, 497 F. Supp. 2d 541, 554 (S.D.N.Y. 2007) (collecting cases)); *see also Hudson Neurosurgery, PLLC v. UMR, Inc.*, 2022 WL 902107, at \*4 (S.D.N.Y. Mar. 28, 2022) (same, and collecting cases); *Manes v. JP Morgan Chase Bank, N.A. et al.*, 2022 WL 671631, at \*7 (S.D.N. Y. Mar. 7, 2022) (“[T]o state a claim for breach of contract, a complaint must allege the specific provisions of the contract upon which the claim is based”); *Spinelli v. Nat’l Football League*, 96 F. Supp. 3d 81, 131 (S.D.N.Y. 2015) (“New York law and the *Twombly-Iqbal* standards of federal pleading require a complaint to identify, in non-conclusory fashion, the specific terms of the contract that a defendant has breached. Otherwise, the complaint must be dismissed.”).

Plaintiff’s allegations fail to rise “above the speculative level.” *Twombly*, 550 U.S. at 555; *see also Elias v. Rolling Stone LLC*, 872 F.3d 97, 107 (2d Cir. 2017) (affirming district court’s dismissal of a claim where the allegations were “too speculative to withstand Defendant’s motion to dismiss.”); *Ramsaroop v. Department of Education*, 2022 WL 376029, at \*6 (S.D.N.Y. Feb. 8, 2022). There are many reasons why Mission would not want to license its technology exclusively to (RC) 2 short of a plan to sell (RC) 2’s docosanol 10% cream or to misuse (RC) 2’s trade secrets. Mission’s technology belongs to Mission. It is a pharmaceutical company involved in, *inter alia*, the development and manufacture of pharmaceuticals as a contract partner for third parties, including—but not limited to—(RC) 2. Dkt. No. 8 ¶ 2. (RC) 2 states that in asking for the exclusive license, it “simply sought the right to use technology relating to the



actual manufacture of the Product so that [it] was not unreasonably tethered to Mission in the event Mission sought to impose unreasonable price hikes” and that “a license is essentially a check on the parties’ future negotiation tactics and it is exclusively limited to uses relating to the Product.” Dkt. No. 42 at 15; Dkt. No. 43 at 21. But that may be precisely the point. Mission was not obligated by the NDA—or by any other agreement between the parties—to bind itself in advance to providing (RC) 2 with Mission’s own technology at the price of (RC) 2’s choosing. (RC) 2 acknowledges as much. *See* Oral Arg. Tr. at 23–24 (“There were two revisions we proposed, one was the exclusive field-of-use license provision . . . , as part of a negotiation we thought was being done in good faith. It wasn’t a demand by any stretch. I don’t think we believe we had the right to demand anything. It was a proposal about how to modify the agreement . . .”). If (RC) 2 wanted or needed such a commitment in order to make the project worthwhile from its perspective, it could and should have bargained for such a commitment in advance; none of the allegations of the Complaint suggest that it did so. Mission’s refusal to agree to such an exclusive license well into the project does not alone constitute a breach of any existing agreement of the parties, even if such refusal proves inconvenient or troublesome to (RC) 2; much less does it mean that Mission is using RC (2)’s confidential information in a way that violates the NDA. Before subjecting Mission to the burden of discovery, RC (2) must allege facts sufficient to make its claim plausible and not just possible. (RC) 2 has alleged no such facts here.

## **2. Count 2: Breach of the Proposal Agreement**

(RC) 2’s second cause of action alleges that Mission breached the Proposal Agreement. (RC) 2 does not identify any provision of the Proposal Agreement that it claims Mission violated. It focuses on the requirement in the Proposal Agreement that Mission conduct stability testing of the three batches. It alleges that, upon information and belief, that “with the exception

of the stability tests that form the basis of its breach of contract claims, Mission has performed the required stability tests for each of the three batches.” *Id.* ¶ 91. The suggestion is that Mission has failed to conduct some of the required stability tests in violation of the Proposal Agreement.

Innuendo and suggestion does not substitute for allegation of fact under *Twombly*, particularly when that innuendo is contradicted by the positive facts alleged in the Complaint. (RC) 2 does not allege facts that there are any stability tests that Mission was required to perform that it did not perform or did not perform in a timely manner. (RC) 2 affirmatively admits that Mission “initiated the stability testing for 39X21 on June 21, 2021, and . . . initiated the stability tests for 40X21 and 41X21 on July 12, 2021.” Dkt. No. 8 ¶ 90. (RC) 2 also alleges that Mission’s “communications suggest that it has timely initiated the six-month stability testing.” *Id.* ¶ 96. (RC) 2 contends that Mission’s “representations . . . confirm that it is willing to cease compliance with its obligations in the middle of performance,” and it expresses concern that “it is not clear whether Mission will complete the six-month stability testing for 39X21,” *id.* ¶ 96, but (RC) 2 does not state that Mission actually has failed to do anything it was required to do or that Mission has failed to timely perform any of those requirements.<sup>4</sup>

---

<sup>4</sup> (RC) 2 also claims in its briefing that Mission is in breach based on failure to perform in-scope IVRT testing and to prepare the ANDA application, as well as based on its requiring that communications go through outside counsel, rather than through the Account Manager, who the Proposal Agreement provides would be the primary point of contact between the parties. Dkt. No. 8-2 § 5. But such allegations appear nowhere in the Complaint. There is no allegation that, at this stage of the process and before the validation and the other testing is completed, Mission has an obligation to conduct IVRT testing or to prepare the ANDA application. Indeed, the Complaint makes clear that the ANDA application cannot be prepared and submitted until after the other testing is completed. (RC) 2 points to paragraph 81 of the Complaint as alleging breach by failure to prepare the ANDA application; paragraph 81 states that “Mission’s statements through its outside counsel further confirm that Mission is intending to continue not to comply with its obligations under the Proposal Agreement, at least because Mission has represented that it intends not to prepare and submit the paperwork for the ANDA process.” Dkt. No. 8 ¶ 81.

The heart of (RC) 2’s complaint is that Mission failed to respond to (RC) 2’s request that by December 22, 2021 it confirm that it would be complying with its obligations under the Proposal Agreement. Dkt. No. 8 ¶ 145; *see also id.* ¶ 99 (“While Mission’s communications suggest that it has gathered the materials and begun to perform the six-month stability testing, it has not confirmed that it will complete the necessary testing as is required by the Proposal Agreement.”); *id.* ¶ 109 (alleging that communications from Mission’s counsel “do not confirm that Mission will complete stability testing of 39X21, or perform any other necessary testing on 39X21”); *id.* ¶ 141 (alleging that Mission “did not respond in substance” to its three emails on December 16, 2021, December 17, 2021, and December 21, 2021).

There is no requirement under the Proposal Agreement, however, that Mission respond to a unilateral demand from (RC) 2 within a specified time period on pain that if it does not do so it will be considered in default of the agreement. Thus, (RC) 2 had no contractual right to demand that Mission respond by December 22, 2021, and Mission had no contractual obligation to do so. Mission’s failure to respond with a written confirmation by December 22, 2021 thus does not constitute a breach of contract and does not entitle (RC) 2 to contractual remedies.

---

This allegation sounds in anticipatory repudiation, not in breach of contract, and (RC) 2 has stated that it is not pressing an anticipatory repudiation claim. The Complaint is devoid of any allegations that Mission has breached by failing to prepare the ANDA application. It is similarly devoid of any reference to failure to perform IVRT testing and of any allegations of breach by requiring that communications go through outside counsel. A party may not survive a motion to dismiss by pointing to other claims it has—that may or may not state a claim—that are not pleaded in the operative complaint but are raised only in the party’s briefing or at oral argument. *See Peffers v. Stop & Shop Supermarket Co. LLC*, 2015 WL 5460203, at \*5 n.5 (S.D.N.Y. June 9, 2015) (“[A]llegations added in opposition to a motion to dismiss cannot cure defects in the operative pleading.”); *Danser v. Bagir International, Inc.*, 2013 WL 5220902, at \*3 (S.D.N.Y. Sept. 17, 2013) (“[T]he court disregards those allegations . . . because it is well-settled that a claim for relief may not be amended by the briefs in opposition to a motion to dismiss.”).

New York law permits a contracting party, under limited circumstances, to demand “adequate assurance of due performance” from its contractual counterparty and relieves a party who does not receive such assurance from certain contractual obligations. *See Norcon Power Partners v. Niagara Mohawk Power Corp.*, 705 N.E.2d 656, 660 (N.Y. 1998). In particular, under the Uniform Commercial Code (“UCC”) and in limited non-UCC cases, a party can demand in writing adequate assurance of due performance when reasonable grounds for insecurity arise with respect to the performance of the other party. U.C.C. § 2-609(1). If the demand for adequate assurance is commercially reasonable, the party may suspend any performance for which he has not already received the agreed sum until he receives such assurance. *Id.* In more limited circumstances, the failure of the counterparty to provide adequate assurance can constitute a repudiation of the contract, giving rise to contract remedies: “After receipt of a justified demand failure to provide within a reasonable time not exceeding thirty days such assurance of due performance as is adequate under the circumstances of the particular case is a repudiation of the contract.” *Id.* § 2-609(4). The doctrine exists to address the dilemma when an “apparently breaching party’s actions are equivocal or less certain” and “the nonbreaching party . . . senses an approaching storm cloud, affecting the contractual performance.” *Norcon*, 705 N.E.2d at 659. Absent the doctrine, the promisee is on the horns of a dilemma. If it sues too soon, it is at risk that a court will find “the apparent repudiation not sufficiently clear and unequivocal to justify nonperformance. If, on the other hand, the promisee continues to perform after perceiving an apparent repudiation, and it is subsequently determined that an anticipatory repudiation took place, the promisee may be denied recovery for post-repudiation expenditures because of his or her failure to avoid those expenses as part of a reasonable effort to mitigate damages after the repudiation.” *Id.* (quoting Gregory S. Crespi, *The*

*Adequate Assurance Doctrine after U.C.C. § 2-609: A Test of the Efficiency of the Common Law*, 38 Vill. L. Rev. 179, 183 (1993)). The New York Court of Appeals has extended the doctrine beyond contracts for the sale of goods to contracts for the sale of similar products pursuant to a “long-term commercial contract . . . , which is complex and not reasonably susceptible of all security features being anticipated, bargained for and incorporated in the original contract.” *Id.* at 662.

The doctrine of adequate assurance does not help RC (2) here.<sup>5</sup> First, “[s]ince *Norcon* was decided, courts have been ‘reluctant to extend the right to demand adequate assurances of performance beyond insolvency settings, contracts for the sale of goods governed by the Uniform Commercial Code, and closely analogous contracts.’” *Ricatto v. M3 Innovations Unlimited, Inc.*, 2020 WL 2306480, at \*4 (S.D.N.Y. May 8, 2020) (quoting *Jordan v. Can You Imagine, Inc.*, 485 F. Supp. 2d 493, 502 n.5 (S.D.N.Y. 2007) and citing cases); *see also Merrill Lynch Intern. v. XL Capital Assur. Inc.*, 564 F.Supp.2d 298, 306 (S.D.N.Y. 2008) (stating “it is far from clear that the doctrine of adequate assurance applies at all in this situation. . . . [T]he New York Court of Appeals has extended the doctrine beyond the U.C.C. context only in limited circumstances, viz., where it found the contract at issue to be closely analogous to one for the sale of goods.”); *Peng v. Willets Point Asphalt Corp.*, 915 N.Y.S.2d 878 (2d Dep’t 2011) (“The Supreme Court erred in determining that ‘[t]he doctrine known as demand for adequate assurances of future performance’ is applicable to this matter.” (internal citations omitted)); *Bank of New York v. River Terrace Assocs., LLC*, 804 N.Y.S.2d 728, 729 (2005) (explaining that

---

<sup>5</sup> Although (RC) 2’s allegations sound in adequate assurance, it does not formally invoke this doctrine.

“[t]he Court of Appeals has enjoined the courts to proceed warily in extending this UCC doctrine [of adequate assurance] to the common law of this State”).

Second, (RC) 2 invokes Mission’s failure to respond to (RC) 2’s deadline for a response not to justify (RC) 2’s own non-performance (which is what the doctrine of adequate assurance permits) but to assert that Mission has breached, or anticipatorily repudiated, the Proposal Agreement. In short, (RC) 2’s second claim sounds in anticipatory repudiation. But, in those circumstances, even assuming the doctrine of adequate assurance applied, Mission would not be required necessarily to respond on (RC) 2’s timetable. It would have such “reasonable time not exceeding thirty days as is adequate under the circumstances of the particular case.” U.C.C. § 2-609(4). There is no allegation here that the response time that (RC) 2 demanded was a reasonable time under the circumstances of the case.

Finally, and critically, Mission did respond. As late as December 28, 2021, (RC) 2’s counsel emailed Mission’s counsel, asking for confirmation that Mission would conduct the stability tests, reflecting at least (RC) 2’s view that Mission had not yet at that point clearly and unequivocally repudiated its contractual obligations. *Id.* at 4. The following day, Mission’s counsel wrote to (RC) 2’s counsel with the confirmation that Mission was in the process of conducting such testing and would fulfill its contractual obligations. Dkt. No. 8-6 at 2. Under no circumstances is the period of only a few hours from the demand for adequate assurance—and less than two weeks from the initial such demand—is the provision of such assurance unreasonable.<sup>6</sup>

---

<sup>6</sup> The letter from counsel states that Mission will not itself perform the non-stability testing and that (RC) 2 should obtain the third-party vendors to conduct that testing for which Mission will provide the samples. But (RC) 2’s own allegations are that Mission was to engage third parties to perform that testing. *Id.* ¶ 102. (RC) 2 does not identify a provision of the Proposal Agreement that required Mission itself to perform the non-stability testing. Nor does (RC) 2

**C. Count 3: Anticipatory Breach of the Proposal Agreement**

(RC) 2's third claim for relief is explicitly for anticipatory breach of contract. (RC) 2 claims that James' emails of September 3, 2021 and September 10, 2021 related to the TTA communicated a threat that Mission would cease its ongoing compliance with the Proposal Agreement unless (RC) 2 executed the TTA exactly as Mission proposed and without any room for negotiations or amendments, Dkt. No. 8 ¶ 153, and that Mission's outside counsel's statement that Mission would not itself perform "any future work of any type," constitutes an unequivocal statement that Mission intends to breach its obligations under the Proposal Agreement, *id.* ¶ 154.

(RC) 2 does not defend this claim in its opposition to the motion to dismiss, and it stated at oral argument that it is no longer pressing a claim for anticipatory repudiation. *See* Oral Arg. Tr. at 21. Therefore, this claim is deemed abandoned. *See Johannes Baumgartner Wirtschafts-Und Vermögensberatung GmbH v. Salzman*, 969 F. Supp. 2d 278, 290 (E.D.N.Y. 2013) ("[A] Court need not entertain an argument that was not briefed."); *Feingold v. RageOn, Inc.*, 472 F. Supp. 3d 94, 97 (S.D.N.Y. 2020) (same).

**CONCLUSION**

The motion to dismiss is GRANTED without prejudice. If Plaintiff intends to file an amended complaint, it may do so within two weeks; if it does not, the case will be closed. The application for a temporary restraining order is DENIED as moot.

The Clerk of Court is respectfully directed to close Dkt. Nos. 34, 49, and 57.

---

identify a provision that would preclude Mission from asking (RC) 2 to find the third-party vendor if, as appears from the documents incorporated by reference, (RC) 2 has frustrated Mission's performance of the contract by not agreeing to Mission's choice of third-party vendors.

SO ORDERED.

Dated: July 5, 2022  
New York, New York

A handwritten signature in black ink, appearing to read 'L. Liman', is written over a horizontal line.

LEWIS J. LIMAN  
United States District Judge